National Cancer Institute
National Institutes of Health
U.S. Department of Health and Human Services

NCI Biorepository Coordinating Committee Workshop
Best Practices for Establishing and Maintaining
Biorepositories That Support Cancer Research

July 18-20, 2005

Park Hyatt Washington
Washington, DC

APPENDIX B:

AGENDA

Workshop Purpose

To identify and recommend Best Practices for the establishment and maintenance of human biospecimen and associated clinical data repositories designed to broadly support cancer research and development. These Best Practices will address biorepository operational, infrastructural, and informatics requirements, as well as the procedural boundaries that ensure compliance with bioethical, legal, biosafety, quality assurance, and quality control guidelines.

Monday, July 18

4:00 p.m. - 9:00 p.m.	**Registration**	*Park Ballroom Foyer*
5:00 p.m. - 5:30 p.m.	**Welcome** Anna D. Barker, Ph.D. National Cancer Institute Mark A. Rubin, M.D. Dana-Farber Cancer Institute	*Park Ballroom*
5:30 p.m. - 5:45 p.m.	**Workshop Background and Overview** Julie Schneider, D.Phil. National Cancer Institute Jim Vaught, Ph.D. National Cancer Institute	

5:45 p.m. - 6:30 p.m. **Dinner** *Park Ballroom*

6:30 p.m. - 9:00 p.m. **Opening Session** *Park Ballroom*
Dinner Meeting **Plenary: The Purpose and Use of Biorepositories**

Session Chairs:
Anna D. Barker, Ph.D.
National Cancer Institute

Mark A. Rubin, M.D.
Dana-Farber Cancer Institute

Goals for the Session:
- Provide an Overview of Existing Repositories in the United States.
- Describe the major types of science supported by repositories, and introduce the concept of biorepository classification.
- Clarify the mission and charge for the workshop.

Overview of the State of Repositories in the United States (15 minutes)
Elisa Eiseman, Ph.D.
RAND Corporation

The Basic Science Perspective (15 minutes)
Carolyn Compton, M.D., Ph.D.
National Cancer Institute

The Population Science Perspective (15 minutes)
Thomas A. Sellers, Ph.D., M.P.H.
H. Lee Moffitt Cancer Center and Research Institute

The Clinical Science Perspective (15 minutes)
H. Kim Lyerly, M.D.
Duke Comprehensive Cancer Center

The Patient Perspective (15 minutes)
Paula Kim
Paula Kim Consulting

Mary Lou Smith, J.D.
Research Advocacy Network

Question-and-Answer Session (Open Microphone) (20 minutes)
Moderators:
Anna D. Barker, Ph.D.
National Cancer Institute

Mark A. Rubin, M.D.
Dana-Farber Cancer Institute

Charge and Mission of the Workshop (15 minutes)
Anna D. Barker, Ph.D.
National Cancer Institute

Mark A. Rubin, M.D.
Dana-Farber Cancer Institute

Tuesday, July 19

8:00 a.m. - 8:15 a.m.	**Good Morning and Refresh Session From the Previous Evening**	*Park Ballroom*
	Daily Charge Anna D. Barker, Ph.D. National Cancer Institute	
	Mark A. Rubin, M.D. Dana-Farber Cancer Institute	
8:15 a.m. - 9:30 a.m.	**Morning Plenary: Cross-Cutting Issues for Biorepositories** *Session Chair:* Frank P. Simione, M.S. American Type Culture Collection	*Park Ballroom*
	Introduction (5 minutes) Frank P. Simione, M.S. American Type Culture Collection	
	Report From the Ethical, Legal, and Policy Workshop (15 minutes) Rihab Yassin, Ph.D. National Cancer Institute	
	Biorepository 911: Biosafety (15 minutes) William E. Grizzle, M.D., Ph.D. University of Alabama at Birmingham	
	The Need for Strong Quality Assurance and Quality Control Practices (15 minutes) Daniel W. Chan, Ph.D. Johns Hopkins School of Medicine	
	Key Requirements for a Biorepository Informatics System (15 minutes) Kenneth H. Buetow, Ph.D. National Cancer Institute	
	Discussion (10 minutes) Frank P. Simione, M.S. American Type Culture Collection	
9:30 a.m. - 9:45 a.m.	**Break**	

9:45 a.m. - 11:15 a.m. **Plenary: Analytical Methods Supported by Repositories** *Park Ballroom*

Session Chairs: (5/5 minutes)
Elaine S. Jaffe, M.D.
National Cancer Institute

Glen Hortin, M.D., Ph.D.
Clinical Center, National Institutes of Health

Goals for the Session:

- Identify and review the analytical techniques currently used to study samples stored in repositories. The sample specifications of these individual analytical techniques will form the basis for biospecimen collection, processing, storage, retrieval, and dissemination.
- Review specimen-specific QA/QC procedures to ensure the quality of the biospecimen and its associated data.
- Discuss the challenges of collecting data and maintaining biospecimen integrity.

Analysis of DNA (10 minutes)
Mark Cosentino, Ph.D., D.P.M.
National Cancer Institute

Analysis of RNA (10 minutes)
Janet A. Warrington, Ph.D.
Affymetrix

Analysis of Protein (10 minutes)
Katherine R. Calvo, M.D., Ph.D.
National Cancer Institute

Analysis of Tissue (10 minutes)
William E. Grizzle, M.D., Ph.D.
University of Alabama at Birmingham

Analysis of Other Analytes (10 minutes)
Susan E. Hankinson, Sc.D.
Harvard Medical School

Use of the Clinical Data (10 minutes)
David Hunter, Sc.D., M.B.B.S.
Harvard School of Public Health

Closing Remarks and Discussion (15 minutes)
Elaine S. Jaffe, M.D.
National Cancer Institute

Glen Hortin, M.D., Ph.D.
Clinical Center, National Institutes of Health

11:15 a.m. - 11:30 a.m.

Best Practices and Unresolved Issues for Biospecimen Collection, Processing, Storage, Retrieval, and Dissemination *Park Ballroom*

Six Breakout Working Groups
Session Chair: (10 minutes)
Leslie Bernstein, Ph.D.
University of Southern California

Goals for the Session:

- Recommend specimen-specific Best Practices for collection, processing, storage, retrieval, and dissemination of biospecimens.
- Identify specimen-specific QA/QC procedures to ensure biospecimen and data quality.
- Discuss requirements for the biorepository informatics system at each stage of the biospecimen life cycle.
- Define the collection and processing of clinical and epidemiological data associated with biospecimens.
- Identify gaps in our scientific knowledge about specimen-specific issues.
- Identify technological barriers to achieving specimen-specific Best Practices.
- Recommend research directions to close gaps in our scientific knowledge and overcome technical barriers.

11:30 a.m. - 12 noon

Gather and Eat Lunch
Move to Breakout Rooms

12 noon - 1:30 p.m.

Best Practices and Unresolved Issues for Biospecimen Collection, Processing, Storage, Retrieval, and Dissemination Working Groups

Blood *Tivoli I*
Chair: Susan E. Hankinson, Sc.D.
Harvard Medical School

Co-Chair: Jim Vaught, Ph.D.
National Cancer Institute

Tissue *Tivoli II*
Chair: Katherine C. Sexton, M.B.A.
University of Alabama at Birmingham

Co-Chair: Andrew Hruszkewycz, M.D., Ph.D.
National Cancer Institute

Other Biospecimens *Hyde Park I and II*
Chair: Neil Caporaso, M.D.
National Cancer Institute

Co-Chair: Shannon M. Lemrow, Ph.D.
National Cancer Institute

Clinical Data Collection *Hyde Park III and IV*
Chair: Graham A. Colditz, M.D., Dr.P.H.
Harvard Medical School

Co-Chair: L. Michelle Bennett, Ph.D.
National Cancer Institute

Informatics *St. James Park*
Chair: Mark A. Watson, M.D., Ph.D. *(Mezzanine Level)*
Washington University School of Medicine

Co-Chair: Ian Fore, D.Phil.
National Cancer Institute

QA/QC *Green Park*
Chair: Timothy J. O'Leary, M.D., Ph.D. *(Mezzanine Level)*
U.S. Department of Veterans Affairs

Co-Chair: Asad Umar, Ph.D., D.V.M.
National Cancer Institute

1:30 p.m. - 2:00 p.m. **Break**

2:00 p.m. - 4:00 p.m. **Plenary: Best Practices and Unresolved Issues for Biospecimen Collection, Processing, Storage, Retrieval, and Dissemination Working Groups—Working Group Reports** *Park Ballroom*
Session Chair:
Leslie Bernstein, Ph.D.
University of Southern California

Introduction (5 minutes)
Leslie Bernstein, Ph.D.
University of Southern California

Blood (15 minutes)
Susan E. Hankinson, Sc.D.
Harvard Medical School

Tissue (15 minutes)
Katherine C. Sexton, M.B.A.
University of Alabama at Birmingham

Other Biospecimens (15 minutes)
Neil Caporaso, M.D.
National Cancer Institute

Clinical Data Collection (15 minutes)
Graham A. Colditz, M.D., Dr.P.H.
Harvard Medical School

Informatics (15 minutes)
Mark A. Watson, M.D., Ph.D.
Washington University School of Medicine

QA/QC (15 minutes)
Timothy J. O'Leary, M.D., Ph.D.
U.S. Department of Veterans Affairs

Discussion (25 minutes)
Leslie Bernstein, Ph.D.
University of Southern California

4:00 p.m. - 4:10 p.m. **Establishing Repository Evaluation and Monitoring Criteria** (10 minutes) *Park Ballroom*
Lance A. Liotta, M.D., Ph.D.
George Mason University

Goals for the Session:
- Develop criteria to evaluate repositories based on a repository classification framework.
- Identify specimen-specific QA/QC procedures to evaluate the quality of the biospecimen and the accompanying data.
- Discuss the role of the biorepository informatics system in repository evaluation.
- Discuss the required reporting functions for the biorepository informatics system.

4:10 p.m. - 4:30 p.m. **Break and Move Into Working Groups**

4:30 p.m. - 6:00 p.m. **Establishing Repository Evaluation and Monitoring Criteria Working Groups**

Blood *Tivoli I*
Chair: Susan E. Hankinson, Sc.D.
Harvard Medical School

Co-Chair: Jim Vaught, Ph.D.
National Cancer Institute

Tissue *Tivoli II*
Chair: Katherine C. Sexton, M.B.A.
University of Alabama at Birmingham

Co-Chair: Andrew Hruszkewycz, M.D., Ph.D.
National Cancer Institute

Other Biospecimens *Hyde Park I and II*
Chair: Neil Caporaso, M.D.
National Cancer Institute

Co-Chair: Shannon M. Lemrow, Ph.D.
National Cancer Institute

Clinical Data Collection *Hyde Park III and IV*
Chair: Graham A. Colditz, M.D., Dr.P.H.
Harvard Medical School

Co-Chair: L. Michelle Bennett, Ph.D.
National Cancer Institute

Informatics *St. James Park*
Chair: Mark A. Watson, M.D., Ph.D. *(Mezzanine Level)*
Washington University School of Medicine

Co-Chair: Ian Fore, D.Phil.
National Cancer Institute

QA/QC *Green Park*
Chair: Timothy J. O'Leary, M.D., Ph.D. *(Mezzanine Level)*
U.S. Department of Veterans Affairs

Co-Chair: Asad Umar, Ph.D., D.V.M.
National Cancer Institute

6:00 p.m. - 7:00 p.m. **Reception**

Wednesday, July 20

8:00 a.m. - 8:15 a.m. **Good Morning and Refresh Session From the Previous Evening** *Park Ballroom*
Daily Charge
Anna D. Barker, Ph.D.
National Cancer Institute

Mark A. Rubin, M.D.
Dana-Farber Cancer Institute

8:15 a.m. - 10:15 a.m. **Plenary: Establishing Repository Evaluation and Monitoring Criteria—Working Group Reports** *Park Ballroom*
Session Chair:
Lance A. Liotta, M.D., Ph.D.
George Mason University

Introduction (5 minutes)
Lance A. Liotta, M.D., Ph.D.
George Mason University

Blood (15 minutes)
Susan E. Hankinson, Sc.D.
Harvard Medical School

Tissue (15 minutes)
Katherine C. Sexton, M.B.A.
University of Alabama at Birmingham

Other Biospecimens (15 minutes)
Neil Caporaso, M.D.
National Cancer Institute

Clinical Data Collection (15 minutes)
Graham A. Colditz, M.D., Dr.P.H.
Harvard Medical School

Informatics (15 minutes)
Mark A. Watson, M.D., Ph.D.
Washington University School of Medicine

QA/QC (15 minutes)
Timothy J. O'Leary, M.D., Ph.D.
U.S. Department of Veterans Affairs

Discussion (25 minutes)
Chair: Lance A. Liotta, M.D., Ph.D.
George Mason University

10:15 a.m. - 10:30 a.m. **Break**

10:30 a.m. - 12 noon **Panel Discussion: Access to Biospecimens** *Park Ballroom*
Session Chair: (5 minutes)
P. Pearl O'Rourke, M.D.
Partners Healthcare System

Goals for the Session:
- Review the ethical and legal framework for access to biospecimens.
- Discuss scientific criteria for allowing researchers access to biospecimens.
- Discuss logistical obstacles to accessing biospecimens.
- Propose solutions to these obstacles.

Panelists/Discussants:
Paula Kim
Paula Kim Consulting

Mark A. Rubin, M.D.
Dana-Farber Cancer Institute

Thomas A. Sellers, Ph.D., M.P.H.
H. Lee Moffitt Cancer Center and Research Institute

Linda K. Weiss, Ph.D.
National Cancer Institute

12 noon - 1:30 p.m.
Luncheon

Plenary: Designing Repositories To Support Research With Emerging Technologies — *Park Ballroom*

Session Chairs:
Carolyn Compton, M.D., Ph.D.
National Cancer Institute

Theodore E. Mifflin, Ph.D.
University of Virginia

Goals for the Session:

- Present an overview of technologies under development or on the horizon that may be adapted for use in the analysis of human biospecimens and associated data.
- Discuss how biorepositories can support research using emerging technologies.
- Discuss how the NCI can prioritize designing repositories to support emerging technologies.

Introductory Remarks (5/5 minutes)
Carolyn Compton, M.D., Ph.D.
National Cancer Institute

Theodore E. Mifflin, Ph.D.
University of Virginia

Panelists/Discussants:
Mark Cosentino, Ph.D., D.P.M.
National Cancer Institute

Michael Hogan, Ph.D.
GenVault Corporation

Lance A. Liotta, M.D., Ph.D.
George Mason University

1:30 p.m. - 1:45 p.m. **Break**

1:45 p.m. - 3:45 p.m. **Priority Setting for Biorepositories: Panel Discussion (Open Microphone)** *Park Ballroom*

Session Chairs: (5/5 minutes)
Robert A. Hiatt, M.D., Ph.D.
University of California, San Francisco

Elaine W. Gunter, MT (ASCP)
Centers for Disease Control and Prevention

Goals for the Session:
- Discuss economic issues relevant to:
  - Establishing
  - Maintaining
  - Retiring repositories
- Provide guidance for NCI-supported repositories.

Introductory Remarks (5/5 minutes)
Robert A. Hiatt, M.D., Ph.D.
University of California, San Francisco

Elaine W. Gunter, MT (ASCP)
Centers for Disease Control and Prevention

Panelists/Discussants:
Stephen A. Buia

Katherine C. Sexton, M.B.A.
University of Alabama at Birmingham

Frank P. Simione, M.S.
American Type Culture Collection

Kathi Shea
SeraCare BioServices

Sholom Wacholder, Ph.D.
National Cancer Institute

3:45 p.m. - 4:15 p.m. **Meeting Wrap-up and Closing** *Park Ballroom*
Anna D. Barker, Ph.D.
National Cancer Institute

Mark A. Rubin, M.D.
Dana-Farber Cancer Institute